UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,764	03/20/2006	Fysh Dadd	22409-00257-US	6613

30678 7590 03/18/2009

CONNOLLY BOVE LODGE & HUTZ LLP
1875 EYE STREET, N.W.
SUITE 1100
WASHINGTON, DC 20006

EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
03/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,764	DADD ET AL.	
	Examiner	Art Unit	
	JESSICA REIDEL	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-17 and 19-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-13,15-17,19-24,26 and 30-32* is/are rejected.

7)☒ Claim(s) *14,25,27-29 and 33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/20/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgment is made of Applicant's preliminary amendment, which was received by the Office on June 20, 2005. Claims 9 and 18 have been cancelled. Claims 1-8, 10-17 and 19-33 are currently pending.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on June 20, 2005 has been acknowledged and considered by the Examiner.

Drawings

3. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office Action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "a resiliently flexible elongate member having a proximal end, *a distal end*, and having *at least one electrode* mounted thereon" must be shown or the feature(s) canceled from the claim(s) (emphasis added). Also, the "adhesive" sealing a lumen of such an elongate member "upon curing" must be shown or the feature(s) canceled from the claim(s). Furthermore, a second portion of the lumen "coated with a material that swells on contact with fluids" must be shown or the feature(s) canceled from the claim(s). The Examiner additionally makes reference to the embodiment of the implantable tissue-stimulating device defined by Claims 1 and 8 and notes that Applicant's drawings fail to show such a device comprising both "a seal" that is pierceable by a stiffening element *and* "a plug member" positionable within the orifice of the lumen (emphasis added). Applicant's drawings also fail to show an elongate member as defined by Claim 1, 8 and 10 having "a second

proximal end" and "a second distal end" where the lumen extends through the elongate member from the orifice "that is positioned at or relatively closer to" the second proximal end than the second distal end. These feature(s) must be shown or the feature(s) canceled from the claim(s). Lastly, with reference being made to Claims 20-24 and 27, a device comprising both a seal/sealing member *and* "a compression member" that is a clip mountable around the elongate member of the device must be shown or the feature(s) canceled from the claim(s) (emphasis added). No new matter should be entered.

5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

6. Claims 5-7, 11, 14 and 19 are objected to because of the following informalities: inadvertent typographical and/or grammatical errors exist rendering the language awkward, confusing, and/or inconsistent. At the fifth line of Claim 5 and the sixth line of Claim 7, the Examiner suggests changing "the method comprising the steps of:" to instead read "the method comprising" in order to avoid antecedent basis problems. Similar changes are also suggested for the preambles of Claims 11 and 19. As to Claim 6, the Examiner suggests revising the claim to read something similar to "The method of manufacturing an implantable tissue-stimulating device of claim 5, further comprising positioning the stiffening element within the lumen of the

elongate member such that the stiffening element extends from within the lumen back out through the orifice of the lumen" in order to clarify the claim and to correct typographical and/or grammatical errors currently present. As to Claim 14, line 2, the Examiner suggests changing "that substantially matches the shape of" to read "that substantially matches a shape of" instead in order to avoid an antecedent basis problem. As to Claim 19 it appears that this claim should depend from Claim 7, however the claim currently fails to recite any dependency. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. ***Claims 8, 10, 11, 20-24 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.*** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's originally-filed disclosure adequately describes "a seal" that is pierceable by a stiffening element where the seal substantially seals a lumen of an implantable tissue-stimulating device following removal of the stiffening element from the lumen (see, for example, Figs. 3 and 4b and page 20, line 15 through page 21, line 15 of the originally-filed disclosure). The originally-filed disclosure also adequately describes alternative embodiments where an orifice of the lumen is sealed by a plug (see, for example, Figs. 5 and 6a-6d and page 21, line 16 through page 22, line 33 of the originally-filed disclosure) or by a compression member (see, for example, Figs. 16a and 16b and page 25, line 10 through page 26, line 20 of the originally-filed disclosure). The Examiner is unable to find, however, at any portion of Applicant's originally-filed disclosure a described embodiment of an implantable tissue-stimulating device comprising both "a seal" as defined by Applicant's Claim 1 *and* "a plug member" as defined by Applicant's Claim 8 (emphasis added). Similar analysis and/or reasoning is applicable to the claimed method of Claim 11. The Examiner is also unable to find,

at any portion of Applicant's originally-filed disclosure, a described embodiment of an implantable tissue-stimulating device comprising both "a seal" as defined by Applicant's Claim 1 *and* "a compression member" as defined by Applicant's Claim 27 nor is the Examiner able to find a described embodiment of an implantable tissue-stimulating device comprising both "a sealing member" as defined by Applicant's Claim 12 *and* "a compression member" as defined by Applicant's Claims 20-24. Furthermore, with regards to Claim 10, the Examiner is also unable to find any written description of the "second proximal end" and the "second distal end" of the elongate member as defined the claim at any portion of the originally-filed disclosure.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

10. ***Claims 2, 7, 11, 15-17, 19 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.*** Claim 2 is considered indefinite since neither of Claims 1 or 2 positively recite that the devices comprise "a stiffening element" and since the preamble of Claim 2 recites "The implantable tissue-stimulating device of claim 1, *wherein*" (wherein). It is sufficiently unclear whether or not Applicant intends to claim a device as defined by Claim 1 where the device further comprises "a stiffening element". Clarification in response to this Office Action is respectfully requested.

11. Claim 7 recites the limitation "the stiffening element" in line 10 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claims 11 and 19 depend from Claim 7 and the deficiencies of Claim 7 are imputed to all dependant claims. Furthermore, with regards to Claim 19, it is sufficiently unclear if the "seal that at least substantially seals the lumen" recited by Claim 7 is the same element as the "sealing member" recited by Claim 19. Clarification in response to this Office Action is respectfully requested.

12. Claim 15 recites the limitation "said distal end" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claims 16 and 17 depend from Claim 15 and the deficiencies of Claim 15 are imputed to all dependant claims.

13. As to Claim 26, it is unclear whether or not the recited "at least one first portion" is the same as or synonymous with the recited "first portion having a first diameter" of Claim 25.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. ***Claims 1-8, 10-13, 19-23, 31 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuzma et al. (U.S. 7,315,763) (herein Kuzma '763).*** As to Claims 1 and 2, Kuzma '763 expressly discloses a lead, read as an implantable tissue-stimulating device 150 comprising a resiliently flexible elongate covering/carrier, read as an elongate member 60, where the elongate member 60 comprises a proximal end 110 and a distal end 71. Elongate member 60 further comprises "an electrode array 70 that has a plurality of spaced-apart electrode contacts", read as electrodes 200, and a stylet insertion channel, read as a lumen 40, extending through at least a portion of the elongate member 60 from an opening/orifice 50 positioned relatively closer to the proximal end 110 than the distal end 71. Kuzma '763 further discloses that the lumen 40 receives an insertion stylet, read as a stiffening element 77, through the opening/orifice 50 and that the device 150 further comprises an overmold, read as a seal/sealing member 75, that is pierceable by the stiffening element 77 and that is compliant and/or at least partially self-sealing such that the seal/sealing member 75 substantially seals the lumen 40 following removal of the stiffening element 77 from the lumen 40 (see, for example, Kuzma '763 Figs. 1, 3B, 4 and 5, column 3, line 55 through column 4, line 5, column 4, line 34 through column 5, line 4, column 9, line 35 through column 10, line 20, column 11, lines 53-62, and column 12, line 45 through column 13, line 52).

16. As to Claims 3 and 4, in addition to the arguments previously presented, Kuzma '763 explicitly discloses that the seal/sealing member 75 "can be made from an implantable grade silicone, polyurethane or other polymer material and can have a puncture or a slit 76" through the seal/sealing member 75 (see, for example, Kuzma '763 Figs. 4 and 5 and column 13, lines 15-32).

17. As to Claims 5-7, in addition to the arguments previously presented, Kuzma '763 explicitly discloses that a tip of the stiffening element 77 "can be inserted through the slit 76" and into the lumen 40 during implantation of the device 150 and that after implantation, the stiffening element 77 "is withdrawn" from the lumen 40 and the slit 76 in the seal/sealing member 75, being made of compliant material, "will tend to return to its original state, closing the slit" (see, for example, Kuzma '763 Figs. 4 and 5, column 4, line 34 through column 5, line 5 and column 13, lines 15-32).

18. As to Claims 8 and 11, the device 150 of Kuzma '763 further comprises a pin plug, read as a plug member 95, that is positionable within and that seals the opening/orifice 50 of the lumen 40 following withdrawal of the stiffening element 77 from the lumen 40 (see, for example, Kuzma '763 Figs. 7A, column 5, lines 5-14, column 7, lines 17-38, and column 13, line 56 through column 14, line 21).

19. As to Claim 10, in addition to the arguments previously presented, the Examiner considers point "A" depicted in Fig. 1 of the Kuzma '763 reference as being synonymous with the claimed "second proximal end" and considers the disclosed "distal tip 72" as being synonymous with the claimed "second distal end" (see Kuzma '763 Fig. 1, column 9, line 35 through column 10, line 20).

20. As to Claims 12, 13 and 19, when the stiffening element 77 of Kuzma '763 is positioned within lumen 40 of the device 150, the seal/sealing member 75 is considered to be mounted to the stiffening element 77 since the stiffening element is inserted through slit 76 of the seal/sealing member 75. Kuzma '763 expressly discloses that the subsequent withdrawal of the stiffening element 77 from lumen 40, as was previously discussed above, brings such a seal/sealing member 75 "into a position" in which the seal/sealing member 75 "at least substantially seals the lumen" (see, for example, Kuzma '763 Figs. 4 and 5, column 4, line 34 through column 5, line 5 and column 13, lines 15-32).

21. As to Claims 20-23, the device 150 of Kuzma '763 further comprises a malleable ring, read as a compression member 43, mountable around at least a portion of the elongate member 60 (see, in particular, tubing end 51) where the compression member 43 is adjustable between a first, non-crushed configuration in which the compression member 43 does not compress a portion of the lumen 40 and a second, crushed configuration in which the compression member

does compress at least a portion of the lumen 40 (see, for example, Kuzma '763 Fig. 7B, column 5, lines 14-18 and column 14, lines 22-29).

22. As to Claims 31 and 32, the lumen 40, in a region adjacent the opening/orifice 50, decreases in diameter away from the opening/orifice into the elongate member 60 for a length (e.g., towards electrode array 70 having electrodes 200). In particular, Applicant's attention is directed to "the tapering" of the device 150 towards the distal end 71 discussed by Kuzma '763 throughout the reference and depicted in at least Fig. 1 of the reference.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25. ***Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma '763.*** Kuzma '763 does not disclose expressly that the compression member 43 comprise a clip where upon closing and latching of the clip, at least a portion of the lumen 40 is compressed sufficiently to at least substantially seal the lumen. Instead, as previously discussed, compression member 43 comprises a malleable ring, mountable around at least a portion of the elongate member 60 (see, in particular, tubing end 51) where the compression member 43 is adjustable between a first, non-crushed configuration in which the compression member 43 does not compress a portion of the lumen 40 and a second, crushed configuration in which the compression member

does compress at least a portion of the lumen 40 (see, for example, Kuzma '763 Fig. 7B, column 5, lines 14-18 and column 14, lines 22-29).

26. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the compression member 43 of Kuzma '763 such that it comprises a clip where upon closing and latching of the clip, at least a portion of the lumen 40 is compressed sufficiently to at least substantially seal the lumen 40, because Applicant has not disclosed that a compression member comprising such a clip provides an advantage, is used for a particular purpose, or that a compression member comprising such a clip solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the compression member 43 of Kuzma '763, and Applicant's invention, to perform equally well with either the compression member 43 comprising a malleable ring taught by Kuzma '763 or the claimed compression member comprising a clip because both compression members would perform the same function of compressing at least a portion of the lumen 40 to at least substantially seal the lumen 40 equally well. Therefore, it would have been *prima facie* obvious to modify Kuzma '763 to obtain the invention as specified in Claim 24 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Kuzma '763.

27. ***Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma '763 in view of Janke et al. (U.S. 6,240,321) (herein Janke).*** Kuzma '763 discloses the essential features of the claimed invention, as previously discussed, except it is not specified that at least a portion of the lumen 40 be coated with a layer of material that swells following exposure to body fluids. Janke, however, discloses various embodiments of an expandable seal/plug for preventing or limiting further entry of body fluids into and/or through an implantable medical device such as a lead or tissue-stimulating device 180. In particular, Janke teaches that it is well known in the art for at least a portion of a lumen 184 of an implantable lead or tissue-stimulating device 180 to be coated with a layer of material 186 that swells following exposure to body fluids (e.g., an expandable matrix, such as a hydorgel) in order to effectively seal the lead/device 180 upon contact with body fluid without hampering the function of a stiffening stylet that might extend through the length of the lead/device 180 (see, for example, Janke Figs. 3A and 3B, column 2, line 53 through column 3, line 17, column 4, lines 63-66, column 6, lines 32-52,

column 7, lines 12-22 and column 12, lines 20-29). Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device 150 taught by Kuzma '763, such that at least a portion of the lumen 40 is coated with a layer of material that swells following exposure to body fluids as taught by Janke, since such a modification would effectively seal the lumen 40 of the device 150 upon contact with body fluid without hampering the function of a stiffening element 77 that might extend through the length of the device 150.

Allowable Subject Matter

28. Claims 25, 27-29 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

29. Claim 14 would be allowable if rewritten to overcome the Claim Objection(s), set forth in this Office Action and to include all of the limitations of the base claim and any intervening claims.

30. Claim 15-17 and 26 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office Action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

31. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. ***Westlund et al. (U.S. 2002/0077683)*** disclose a proximal and/or distal seal or sealing member for use within a lead assembly. ***Mann et al. (U.S. 6,266,568)*** disclose a compression member for sealing a proximal opening in an electrode array and also discuss in detail the conventionality of resalable puncture seals as they are known in the medical implantable catheter art. ***Bartig et al. (U.S. 2002/0111664)*** teach that an opening in a lead may be sealed once the lead has been properly positioned through the use of either a silicone flap, a hydrophilic material which swells upon fluid contact, or the use of a deployable plug.

32. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JESSICA REIDEL whose telephone number is (571)272-2129. The Examiner can normally be reached on Monday - Friday, 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
March 15, 2009

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766